Test Type: CHRONIC

Species/Strain: MICE/B6C3F1

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)

WITH AVERAGE SEVERITY GRADES[b] 5-(HYDROXYMETHYL)-2-FURFURAL

**CAS Number:** 67-47-0

Pathologist: TOFT, J. - Blackshear, P.

F1\_M3

C Number: C95011B

**Lock Date:** 03/11/2004

Cage Range: ALL

Date Range: ALL

Reasons For Removal: 25021 TSAC 25020 NATD 25019 MSAC

25018 DACC

Removal Date Range: ALL

Treatment Groups: Include ALL

Date Report Reqsted: 11/10/2006

Time Report Reqsted: 09:06:29 First Dose M/F: 08/09/01 / 08/08/01

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Species/Strain: MICE/B6C3F1

Route: GAVAGE

# P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

5-(HYDROXYMETHYL)-2-FURFURAL

**CAS Number:** 67-47-0

Pathologist: TOFT, J. - Blackshear, P.

Date Report Reqsted: 11/10/2006

Time Report Reqsted: 09:06:29 First Dose M/F: 08/09/01 / 08/08/01

B6C3F1 MICE MALE	0 MG/KG	188 MG/KG	375 MG/KG	750 MG/KG
Disposition Summary				
•	50	50	50	<b>50</b>
Animals Initially in Study Early Deaths	50	50	50	50
Dosing Accident				2
Moribund Sacrifice	6	9	4	1
Natural Death	4	6	3	31
Survivors	•	· ·	· ·	0.
Natural Death				1
Terminal Sacrifice	40	35	43	14
Animals Examined Microscopically	50	50	50	49
ALIMENTARY SYSTEM				
Gallbladder	(49)	(50)	(49)	(49)
Infiltration Cellular, Mononuclear Cell	1 [1.0]	1 [1.0]	1 [1.0]	1 [1.0]
Necrosis		1 [3.0]		
Intestine Large, Cecum	(50)	(50)	(50)	(49)
Intestine Large, Colon	(50)	(50)	(50)	(49)
Intestine Small, Duodenum	(50)	(50)	(50)	(49)
Intestine Small, Ileum	(49)	(50)	(50)	(49)
Inflammation, Chronic Active	(50)	1 [2.0]	(50)	(40)
Intestine Small, Jejunum	(50)	(50)	(50)	(49)
Inflammation, Chronic Active Peyer's Patch, Hyperplasia, Lymphoid		2 [2.5]	1 [2.0]	
Liver	(50)	2 [4.0] (50)	(50)	(49)
Basophilic Focus	(30)	(50)	(50)	1
Clear Cell Focus	26	7 21	26	1
Cyst		1 [3.0]		·
Eosinophilic Focus	7	9	16	8
Hematopoietic Cell Proliferation		2 [1.5]		
Infarct	3 [4.0]	2 [4.0]	1 [4.0]	1 [4.0]
Infiltration Cellular, Mononuclear Cell	6 [1.2]	9 [1.3]	6 [1.2]	1 [1.0]
Inflammation, Granulomatous	: -:	1 [3.0]		
Inflammation, Chronic Active	37 [1.1]	30 [1.1]	38 [1.1]	19 [1.0]
Mineralization	1 [2.0]	4.4	1 [1.0]	2 [1.5]
Mixed Cell Focus	5	11	15	3
Pigmentation		1 [2.0]	1 [1.0]	1 [1.0]

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Species/Strain: MICE/B6C3F1

Route: GAVAGE

# P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

5-(HYDROXYMETHYL)-2-FURFURAL

**CAS Number:** 67-47-0

Pathologist: TOFT, J. - Blackshear, P.

Date Report Reqsted: 11/10/2006

Time Report Reqsted: 09:06:29 First Dose M/F: 08/09/01 / 08/08/01

B6C3F1 MICE MALE	0 MG/KG	188 MG/KG	375 MG/KG	750 MG/KG	
Thrombosis			1 [4.0]		
Bile Duct, Hyperplasia			1 [3.0]		
Hepatocyte, Necrosis	2 [1.5]	4 [2.3]	5 [2.2]	1 [2.0]	
Hepatocyte, Tension Lipidosis	1 [1.0]	• •	2 [2.0]	1 [1.0]	
Hepatocyte, Vacuolization Cytoplasmic	31 [1.9]	28 [2.1]	30 [2.1]	10 [1.5]	
Mesentery	(4)	(4)	(4)	(2)	
Pigmentation	` ,	,	1 [2.0]	. ,	
Artery, Inflammation, Chronic Active			1 [3.0]		
Fat, Fibrosis	2 [2.0]	2 [2.5]	2 [2.5]	2 [2.0]	
Fat, Inflammation, Chronic Active	2 [1.5]	3 [2.3]	3 [1.7]	2 [2.0]	
Fat, Mineralization	2 [1.0]	2 [1.0]	3 [2.0]	2 [2.0]	
Fat, Necrosis	2 [4.0]	2 [4.0]	2 [4.0]	2 [4.0]	
Pancreas	(50)	(50)	(50)	(49)	
Acinus, Atrophy	1 [1.0]	2 [4.0]	, ,	, ,	
Artery, Inflammation, Chronic Active	2 [1.5]	1 [2.0]			
Salivary Glands	(50)	(50)	(50)	(49)	
Atrophy	` ,		1 [1.0]	, ,	
Mineralization			1 [1.0]		
Artery, Mineralization	2 [1.5]				
Stomach, Forestomach	(50)	(50)	(50)	(49)	
Inflammation, Chronic Active	1 [2.0]	5 [2.2]	3 [3.3]	2 [2.0]	
Ulcer		1 [4.0]	2 [4.0]		
Epithelium, Hyperkeratosis		2 [1.5]	2 [2.0]	4 [2.3]	
Epithelium, Hyperplasia	1 [3.0]	4 [2.0]	4 [3.3]	4 [2.3]	
Stomach, Glandular	(50)	(50)	(50)	(49)	
Dysplasia		1 [4.0]			
Infiltration Cellular, Mast Cell			1 [4.0]		
Inflammation, Chronic Active		1 [2.0]			
Mineralization		1 [2.0]	2 [1.0]		
Tooth	(12)	(7)	(4)	(1)	
Inflammation, Chronic Active		1 [2.0]			
Malformation	10	3	2	1	
Gingiva, Inflammation, Chronic Active	2 [2.5]				
CARDIOVASCULAR SYSTEM					
Blood Vessel	(3)	(1)	(0)	(1)	
Inflammation, Chronic Active	1 [4.0]		<i>i</i>	(12)	
Heart	(50)	(49)	(50)	(49)	

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Test Type: CHRONIC

Species/Strain: MICE/B6C3F1

Atrophy

Route: GAVAGE

# P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

5-(HYDROXYMETHYL)-2-FURFURAL

**CAS Number:** 67-47-0

Pathologist: TOFT, J. - Blackshear, P.

Date Report Reqsted: 11/10/2006

Time Report Reqsted: 09:06:29 First Dose M/F: 08/09/01 / 08/08/01

Lab: BAT

Cardiomyopathy Inflammation, Chronic Active Mineralization Thrombosis Artery, Inflammation, Chronic Active  ENDOCRINE SYSTEM  Adrenal Cortex Accessory Adrenal Cortical Nodule Degeneration, Fatty Hyperplasia Hypertrophy Subcapsular, Hyperplasia Zona Fasciculata, Hyperplasia Zona Glomerulosa, Hyperplasia	1 [2.0] 1 [1.0] 1 [3.0]	1 [1.0] 1 [2.0]	2 [1.5] 1 [1.0] 1 [4.0] 3 [1.7]	2 [1.0] 4 [1.0]	
Mineralization Thrombosis Artery, Inflammation, Chronic Active  ENDOCRINE SYSTEM  Adrenal Cortex Accessory Adrenal Cortical Nodule Degeneration, Fatty Hyperplasia Hypertrophy Subcapsular, Hyperplasia Zona Fasciculata, Hyperplasia	1 [1.0]		1 [1.0] 1 [4.0]		
Thrombosis Artery, Inflammation, Chronic Active  ENDOCRINE SYSTEM  Adrenal Cortex Accessory Adrenal Cortical Nodule Degeneration, Fatty Hyperplasia Hypertrophy Subcapsular, Hyperplasia Zona Fasciculata, Hyperplasia			1 [4.0]	4 [1.0]	
Artery, Inflammation, Chronic Active  ENDOCRINE SYSTEM  Adrenal Cortex     Accessory Adrenal Cortical Nodule     Degeneration, Fatty     Hyperplasia     Hypertrophy     Subcapsular, Hyperplasia     Zona Fasciculata, Hyperplasia	1 [3.0]	1 [2.0]	1 [4.0] 3 [1.7]		
Adrenal Cortex Accessory Adrenal Cortical Nodule Degeneration, Fatty Hyperplasia Hypertrophy Subcapsular, Hyperplasia Zona Fasciculata, Hyperplasia	1 [3.0]	1 [2.0]	S[1./]		
Adrenal Cortex Accessory Adrenal Cortical Nodule Degeneration, Fatty Hyperplasia Hypertrophy Subcapsular, Hyperplasia Zona Fasciculata, Hyperplasia					
Accessory Adrenal Cortical Nodule Degeneration, Fatty Hyperplasia Hypertrophy Subcapsular, Hyperplasia Zona Fasciculata, Hyperplasia					
Degeneration, Fatty Hyperplasia Hypertrophy Subcapsular, Hyperplasia Zona Fasciculata, Hyperplasia	(49)	(50)	(50)	(49)	
Hyperplasia Hypertrophy Subcapsular, Hyperplasia Zona Fasciculata, Hyperplasia		2 [2.0]	1 [2.0]	, ,	
Hypertrophy Subcapsular, Hyperplasia Zona Fasciculata, Hyperplasia	1 [2.0]				
Subcapsular, Hyperplasia Zona Fasciculata, Hyperplasia				1 [2.0]	
Zona Fasciculata, Hyperplasia	13 [1.8]	20 [1.8]	13 [1.8]	6 [1.7]	
	45 [1.4]	41 [1.4]	46 [1.3]	41 [1.2]	
Zona Glomorulosa, Hyporplasia		4 [1.8]	1 [2.0]		
		1 [2.0]			
Adrenal Medulla	(49)	(50)	(50)	(49)	
Islets, Pancreatic	(50)	(50)	(50)	(49)	
Hyperplasia	1 [2.0]				
Parathyroid Gland	(41)	(48)	(48)	(37)	
Cyst		2 [2.0]		1 [2.0]	
Pituitary Gland	(48)	(50)	(50)	(49)	
Pars Distalis, Cyst	6 [1.5]	2 [2.0]	3 [1.3]	2 [1.5]	
Pars Distalis, Hyperplasia			1 [2.0]		
Thyroid Gland	(50)	(50)	(50)	(49)	
Inflammation, Chronic Active	1 [1.0]	1 [2.0]	1 [2.0]	1 [1.0]	
Follicle, Cyst	5 [2.0]	2 [1.5]	1 [3.0]	1 [2.0]	
Follicle, Degeneration	9 [1.7]	13 [1.8]	9 [1.2]	5 [1.2]	
Follicular Cell, Hyperplasia	17 [1.9]	8 [1.8]	13 [1.8]	6 [1.7]	
GENERAL BODY SYSTEM					
None					
GENITAL SYSTEM					
Coagulating Gland					

1 [3.0]

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Species/Strain: MICE/B6C3F1

Route: GAVAGE

# P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

5-(HYDROXYMETHYL)-2-FURFURAL

**CAS Number:** 67-47-0

Pathologist: TOFT, J. - Blackshear, P.

Date Report Reqsted: 11/10/2006

Time Report Reqsted: 09:06:29 First Dose M/F: 08/09/01 / 08/08/01

B6C3F1 MICE MALE	0 MG/KG	188 MG/KG	375 MG/KG	750 MG/KG	
Inflammation, Chronic Active		1 [2.0]			
Epididymis	(50)	(50)	(50)	(49)	
Atrophy	(50)	(50)	1 [3.0]	(49)	
Granuloma Sperm	1 [4 0]	1 [2 0]	1 [3.0]		
Mineralization	1 [4.0]	1 [3.0]			
	2 [1.5]	(50)	(50)	(40)	
Preputial Gland	(50)	(50)	(50)	(49)	
Infiltration Cellular, Mononuclear Cell	7 (0 7)	0.10.01	1 [1.0]		
Inflammation, Chronic Active	7 [2.7]	3 [3.0]	2 [1.0]		
Bilateral, Duct, Ectasia	40.50.03	<b>7.</b> 10. 01	1 [2.0]	<b>7.</b> 10. 41	
Duct, Ectasia	10 [2.2]	7 [2.3]	7 [2.4]	7 [2.1]	
Prostate	(50)	(50)	(50)	(49)	
Inflammation, Chronic Active		1 [2.0]			
Artery, Inflammation, Chronic Active	1 [2.0]	1 [4.0]			
Seminal Vesicle	(50)	(50)	(50)	(49)	
Atrophy			1 [3.0]		
Inflammation, Chronic Active	1 [2.0]				
Testes	(50)	(50)	(50)	(49)	
Atrophy			1 [3.0]		
Mineralization	2 [1.0]	2 [1.0]	4 [1.0]	1 [1.0]	
Bilateral, Germinal Epithelium,			1 [2.0]		
Degeneration					
Germinal Epithelium, Degeneration			1 [2.0]	2 [1.5]	
EMATOPOIETIC SYSTEM					
Bone Marrow	(50)	(50)	(50)	(49)	
Myeloid Cell, Hyperplasia	` ,	1 [4.0]	. ,	, ,	
Lymph Node	(4)	(3)	(4)	(0)	
Inguinal, Hyperplasia, Lymphoid	1 [2.0]	( )	( )	· ,	
Mediastinal, Hyperplasia, Lymphoid	1 [2.0]	1 [3.0]			
Pancreatic, Hematopoietic Cell	,	1 [2.0]			
Proliferation		. []			
Lymph Node, Mandibular	(49)	(50)	(49)	(48)	
Hyperplasia, Lymphoid	6 [2.8]	4 [2.5]	7 [2.1]	(,	
Lymph Node, Mesenteric	(50)	(49)	(49)	(49)	
Hyperplasia, Lymphoid	2 [2.0]	3 [4.0]	5 [3.2]	( ,	
Infiltration Cellular, Plasma Cell	2 [2.0]	0 [ 1.0]	1 [4.0]		
Spleen	(50)	(50)	(50)	(49)	
Hematopoietic Cell Proliferation	11 [2.5]	16 [2.9]	11 [2.7]	2 [2.5]	
Hematopoletic Cell F Tollieration	11 [2.0]	10 [2.3]	11[2.7]	ک زکان	

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Species/Strain: MICE/B6C3F1

Route: GAVAGE

# P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

5-(HYDROXYMETHYL)-2-FURFURAL

**CAS Number:** 67-47-0

Pathologist: TOFT, J. - Blackshear, P.

Date Report Reqsted: 11/10/2006

Time Report Reqsted: 09:06:29 First Dose M/F: 08/09/01 / 08/08/01

B6C3F1 MICE MALE	0 MG/KG	188 MG/KG	375 MG/KG	750 MG/KG	
Lymphoid Follicle, Hyperplasia Thymus Atrophy Cyst Ectopic Parathyroid Gland	(43) 18 [3.1] 25 [1.3] 2 [2.0]	3 [3.0] (47) 23 [3.1] 19 [1.4] 1 [1.0]	4 [3.0] (47) 16 [3.1] 26 [1.5] 1 [2.0]	(49) 9 [3.1] 23 [1.2]	
INTEGUMENTARY SYSTEM					
Skin Inflammation, Chronic Active Epidermis, Hyperkeratosis Epidermis, Hyperplasia	(50) 2 [4.0] 2 [3.0]	(50) 3 [4.0] 1 [2.0] 2 [3.0]	(50) 2 [3.0] 1 [2.0]	(49)	
Epidermis, Ulcer Subcutaneous Tissue, Inflammation,	2 [4.0]	3 [4.0] 1 [2.0]	1 [4.0]	1 [2.0]	
Chronic Active Subcutaneous Tissue, Mineralization Subcutaneous Tissue, Necrosis				1 [2.0] 1 [4.0]	
MUSCULOSKELETAL SYSTEM					
Skeletal Muscle	(1)	(4)	(1)	(1)	
NERVOUS SYSTEM					
Brain Degeneration	(50)	(50)	(50)	(49) 3 [3.0]	
Artery, Inflammation Cerebrum, Hippocampus Neuron, Necrosis, Focal			1 [2.0]	1 [2.0]	
RESPIRATORY SYSTEM					
Lung Infiltration Cellular, Mononuclear Cell	(50) 1 [2.0]	(50)	(50)	(49)	
Inflammation, Chronic Active Mineralization Pigmentation	4 [1.5]	2 [1.5] 1 [1.0]	2 [2.0] 1 [1.0] 1 [2.0]	4 (0.0)	
Thrombosis				1 [2.0]	

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Species/Strain: MICE/B6C3F1

Route: GAVAGE

#### P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

5-(HYDROXYMETHYL)-2-FURFURAL

**CAS Number:** 67-47-0

Pathologist: TOFT, J. - Blackshear, P.

Date Report Regsted: 11/10/2006

Time Report Regsted: 09:06:29 First Dose M/F: 08/09/01 / 08/08/01

B6C3F1 MICE MALE	0 MG/KG	188 MG/KG	375 MG/KG	750 MG/KG	
Alveolar Epithelium, Hyperplasia	3 [3.0]	1 [2.0]	2 [3.0]	7 [2.0]	
Alveolus, Infiltration Cellular, Histiocyte	3 [3.0] 3 [3.0]	1 [2.0] 1 [3.0]	2 [3.5] 2 [3.5]	7 [2.0]	
Artery, Mediastinum, Inflammation,	3 [3.0]	1 [4.0]	2 [5.5]		
Chronic Active		ا [۲.۰]			
Glands, Inflammation, Chronic Active	1 [2.0]	1 [2.0]			
Nose	(50)	(50)	(50)	(47)	
Edema	1 [4.0]	2 [3.5]	(66)	(11)	
Inflammation, Chronic Active	. [•]	6 [1.3]	18 [1.0]	45 [1.5]	
Polyp, Inflammatory		1 [4.0]	.0[0]	.0 [0]	
Glands, Dilatation	16 [1.9]	22 [1.9]	47 [2.0]	45 [2.0]	
Glands, Hyperplasia	3 [1.7]	7 [2.0]	45 [1.8]	45 [2.9]	
Glands, Inflammation, Chronic Active	4 [1.5]	12 [1.7]	34 [1.6]	43 [1.7]	
Nasolacrimal Duct, Inflammation,	2 [2.0]	1 [1.0]			
Suppurative					
Olfactory Epithelium, Accumulation,	13 [1.7]	17 [1.8]	29 [1.7]	27 [1.4]	
Hyaline Droplet					
Olfactory Epithelium, Degeneration	4 [2.0]	2 [1.5]	17 [1.6]	39 [2.6]	
Olfactory Epithelium, Hyperplasia			2 [1.0]	3 [1.3]	
Olfactory Epithelium, Metaplasia	1 [2.0]	7 [2.1]	38 [1.9]	43 [3.9]	
Respiratory Epithelium, Accumulation,	14 [1.6]	17 [1.5]	23 [1.8]	31 [1.7]	
Hyaline Droplet					
SPECIAL SENSES SYSTEM					
Eye	(50)	(50)	(50)	(49)	
Cornea, Inflammation, Chronic Active	2 [3.0]	1 [2.0]	(66)	(10)	
Harderian Gland	(50)	(50)	(50)	(48)	
Hyperplasia	4 [2.8]	5 [3.4]	1 [4.0]	1 [4.0]	
Inflammation, Chronic Active	1	. [. ]	1 [1.0]	1 -1	
URINARY SYSTEM					
	(50)	(50)	(50)	(40)	
Kidney	(50)	(50)	(50)	(49)	
Hydronephrosis	4 [0 0]	4 [4 0]	2 [0 0]	1 [2.0]	
Infarct	1 [3.0]	1 [4.0]	3 [2.3]		
Metaplasia, Osseous	10 11 01	1 [1.0]	3 [1.3]	20 [4 0]	
Mineralization	43 [1.0]	43 [1.0]	44 [1.0]	29 [1.0]	
Nephropathy Artery, Inflammation, Chronic Active	49 [1.5] 3 [2.7]	48 [1.6]	46 [1.6]	30 [1.1]	
Artery, irinamination, Chronic Active	3 [2.7]	1 [3.0]	3 [3.0]		

a - Number of animals examined microscopically at site and number of animals with lesion b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Test Type: CHRONIC

Species/Strain: MICE/B6C3F1

Route: GAVAGE

# P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

5-(HYDROXYMETHYL)-2-FURFURAL

**CAS Number:** 67-47-0

Pathologist: TOFT, J. - Blackshear, P.

Date Report Reqsted: 11/10/2006

Time Report Reqsted: 09:06:29 First Dose M/F: 08/09/01 / 08/08/01

Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	188 MG/KG	375 MG/KG	750 MG/KG	
Renal Tubule, Cyst Renal Tubule, Dilatation	20 1 [2.0]	12	15		
Renal Tubule, Hyperplasia Renal Tubule, Pigmentation Urinary Bladder Mineralization	(50)	(50)	1 [2.0] 1 [3.0] (50) 1 [1.0]	(49) 1 [1.0]	

\*\*\* END OF MALE \*\*\*

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Species/Strain: MICE/B6C3F1

Route: GAVAGE

# P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

5-(HYDROXYMETHYL)-2-FURFURAL

**CAS Number:** 67-47-0

Pathologist: TOFT, J. - Blackshear, P.

Date Report Reqsted: 11/10/2006

Time Report Reqsted: 09:06:29 First Dose M/F: 08/09/01 / 08/08/01

B6C3F1 MICE FEMALE	0 MG/KG	188 MG/KG	375 MG/KG	750 MG/KG
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	4	5	8	6
Natural Death	7	2	10	22
Survivors				
Terminal Sacrifice	39	42	32	22
Animals Examined Microscopically	50	49	50	50
ALIMENTARY SYSTEM				
Gallbladder	(50)	(48)	(49)	(48)
Infiltration Cellular, Mononuclear Cell	3 [1.7]	2 [2.0]	(10)	(10)
Intestine Large, Cecum	(50)	(49)	(50)	(50)
Lymphoid Tissue, Hyperplasia	1 [3.0]	(12)	(/	()
Intestine Large, Colon	(50)	(49)	(50)	(50)
Artery, Inflammation, Chronic Active	1 [2.0]	(12)	1 [3.0]	()
Intestine Large, Rectum	(50)	(49)	(50)	(50)
Intestine Small, Duodenum	(50)	(49)	(50)	(50)
Intestine Small, Ileum	(50)	(49)	(50)	(49)
Intestine Small, Jejunum	(50)	(49)	(50)	(50)
Peyer's Patch, Hyperplasia, Lymphoid	,	,	1 [4.0]	,
Liver	(50)	(49)	(50)	(50)
Basophilic Focus	, ,	`6 ´	<b>`</b> 5 ´	• •
Clear Cell Focus	1	1		
Eosinophilic Focus	6	14	6	3
Hematopoietic Cell Proliferation	1 [1.0]	2 [1.5]	1 [2.0]	
Hemorrhage			1 [4.0]	
Infiltration Cellular, Mononuclear Cell	32 [1.4]	45 [1.1]	34 [1.2]	27 [1.2]
Inflammation, Granulomatous	1 [2.0]			
Inflammation, Chronic Active	40 [1.1]	45 [1.0]	41 [1.1]	36 [1.1]
Mineralization		1 [4.0]	1 [1.0]	
Mixed Cell Focus	4	5	6	
Pigmentation			1 [2.0]	
Thrombosis			1 [3.0]	
Bile Duct, Cyst			1 [4.0]	
Hepatocyte, Necrosis	2 [2.0]		3 [2.7]	1 [2.0]

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Species/Strain: MICE/B6C3F1

Route: GAVAGE

#### P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

5-(HYDROXYMETHYL)-2-FURFURAL

**CAS Number:** 67-47-0

Pathologist: TOFT, J. - Blackshear, P.

Date Report Regsted: 11/10/2006

Time Report Reqsted: 09:06:29 First Dose M/F: 08/09/01 / 08/08/01

Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	188 MG/KG	375 MG/KG	750 MG/KG	
Hepatocyte, Tension Lipidosis	5 [2.0]	4 [2.0]	2 [2.0]	00 (0.5)	
Hepatocyte, Vacuolization Cytoplasmic Mesentery	34 [2.1] (12)	41 [2.1]	34 [2.1]	28 [2.5]	
Infiltration Cellular, Mononuclear Cell	1 [2.0]	(7)	(6)	(1)	
Artery, Inflammation, Chronic Active	1 [2.0]			1 [3.0]	
Fat, Fibrosis	9 [2.0]	4 [2.3]	3 [2.3]	. [6.6]	
Fat, Inflammation, Chronic Active	6 [2.2]	5 [2.2]	3 [1.7]		
Fat, Metaplasia, Osseous		1 [2.0]			
Fat, Mineralization	6 [1.8]	3 [1.0]	1 [1.0]		
Fat, Necrosis	9 [4.0]	4 [4.0]	3 [4.0]		
Pancreas	(49)	(49)	(50)	(50)	
Cyst				1 [4.0]	
Inflammation, Chronic Active				1 [2.0]	
Acinus, Atrophy	4 [0.0]	1 [4.0]	2 [3.5]		
Acinus, Hypertrophy	1 [2.0]	(40)	(40)	(40)	
Salivary Glands	(49)	(49)	(49)	(43)	
Artery, Inflammation, Chronic Active Stomach, Forestomach	(50)	1 [2.0] (49)	1 [2.0] (50)	1 [3.0] (50)	
Inflammation, Chronic Active	(30)	2 [2.5]	(50)	(30)	
Ulcer		1 [3.0]			
Epithelium, Hyperkeratosis	2 [2.0]	2 [2.5]		1 [2.0]	
Epithelium, Hyperplasia	2 [2.5]	2 [2.5]	2 [1.5]	1 [2.0]	
Stomach, Glandular	(50)	(49)	(50)	(50)	
Mineralization	3 [1.3]	1 [1.0]	1 [1.0]	1 [1.0]	
Tongue	(1)	(0)	(0)	(0)	
CARDIOVASCULAR SYSTEM					
Blood Vessel	(1)	(1)	(3)	(2)	
Aorta, Inflammation, Chronic Active	` '	` '	(-/	1 [3.0]	
Heart	(50)	(49)	(50)	(50)	
Cardiomyopathy	1 [1.0]		1 [2.0]		
Mineralization		1 [1.0]			
Thrombosis			1 [4.0]		
Artery, Inflammation, Chronic Active	4.54.03	3 [2.0]	2 [2.0]	1 [2.0]	
Valve, Inflammation, Suppurative	1 [4.0]				

#### **ENDOCRINE SYSTEM**

a - Number of animals examined microscopically at site and number of animals with lesion b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Species/Strain: MICE/B6C3F1

Route: GAVAGE

# P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

5-(HYDROXYMETHYL)-2-FURFURAL

**CAS Number:** 67-47-0

Pathologist: TOFT, J. - Blackshear, P.

Date Report Reqsted: 11/10/2006

Time Report Reqsted: 09:06:29 First Dose M/F: 08/09/01 / 08/08/01

Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	188 MG/KG	375 MG/KG	750 MG/KG	
Adrenal Cortex	(50)	(49)	(50)	(49)	
Accessory Adrenal Cortical Nodule	(66)	2 [2.5]	1 [2.0]	(10)	
Hematopoietic Cell Proliferation		- [0]	1 [2.0]		
Mineralization			1 [2.0]		
Subcapsular, Hyperplasia	48 [2.0]	49 [2.0]	50 [2.0]	49 [1.9]	
Zona Fasciculata, Hyperplasia		1 [2.0]	2 [1.5]	1 [2.0]	
Adrenal Medulla	(50)	(49)	(50)	(49)	
Hyperplasia			1 [3.0]		
Islets, Pancreatic	(50)	(49)	(50)	(50)	
Hyperplasia	2 [2.5]				
Parathyroid Gland	(43)	(41)	(33)	(36)	
Cyst	2 [2.0]				
Pituitary Gland	(49)	(49)	(47)	(44)	
Pars Distalis, Angiectasis	1 [1.0]			1 [2.0]	
Pars Distalis, Cyst		2 [1.5]			
Pars Distalis, Hyperplasia	7 [2.0]	11 [2.4]	4 [1.8]	(47)	
Thyroid Gland	(48)	(49)	(49)	(47)	
Ectopic Thymus	4 [4 []	1 [2.0]	1 [2.0]	0.10.51	
Inflammation, Chronic Active	4 [1.5]	7 [1.3]	5 [1.6]	2 [2.5]	
Ultimobranchial Cyst	2 [2.0]	2 [2.5]	1 [2.0]	1 [2 0]	
Follicle, Cyst Follicle, Degeneration	2 [2.0] 10 [1.9]	2 [2.5] 14 [2.1]	15 [1.7]	1 [2.0] 4 [2.0]	
Follicular Cell, Hyperplasia	10 [1.9]	14 [2.1]	15 [1.7]	4 [2.0] 3 [2.0]	

#### **GENERAL BODY SYSTEM**

None

GENITAL SYSTEM				
Clitoral Gland Inflammation, Chronic Active	(50)	(49)	(49) 1 [1.0]	(47)
Ovary	(50)	(48)	(49)	(48)
Atrophy	12 [3.2]	5 [2.8]	14 [3.0]	20 [3.2]
Cyst	9	14	19	11
Hyperplasia, Adenomatous			1 [2.0]	
Mineralization	2 [1.0]	1 [2.0]		1 [1.0]
Pigmentation	5 [1.8]	3 [1.3]		2 [1.5]
Bilateral, Cyst	2	1		

a - Number of animals examined microscopically at site and number of animals with lesion

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Species/Strain: MICE/B6C3F1

Route: GAVAGE

# P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

5-(HYDROXYMETHYL)-2-FURFURAL

**CAS Number:** 67-47-0

Pathologist: TOFT, J. - Blackshear, P.

Date Report Reqsted: 11/10/2006

Time Report Reqsted: 09:06:29 First Dose M/F: 08/09/01 / 08/08/01

B6C3F1 MICE FEMALE	0 MG/KG	188 MG/KG	375 MG/KG	750 MG/KG	
Oviduct	(2)	(1)	(2)	(0)	
Infiltration Cellular, Mononuclear Cell	1 [2.0]	(15)	(==)	()	
Uterus	(50)	(49)	(50)	(50)	
Angiectasis Hemorrhage			1 [4.0]	1 [3.0]	
Inflammation, Chronic Active			1 [2.0]		
Thrombosis			1 [2.0]	1 [3.0]	
Endometrium, Hyperplasia, Cystic	40 [3.1]	43 [3.0]	42 [2.7]	32 [2.3]	
Lymphatic, Angiectasis		1 [4.0]			
EMATOPOIETIC SYSTEM					
Bone Marrow	(49)	(49)	(50)	(50)	
Lymph Node	(10)	(7)	(3)	(3)	
Mediastinal, Hyperplasia, Lymphoid	6 [3.0]	1 <u>[</u> 4.0]	( )	1 [2.0]	
Renal, Hematopoietic Cell Proliferation	1 [4.0]				
Lymph Node, Mandibular	(49)	(49)	(46)	(43)	
Hyperplasia, Lymphoid	3 [3.0]	9 [3.4]	2 [2.5]	2 [3.0]	
Infiltration Cellular, Mast Cell			1 [2.0]		
Pigmentation	1 [2.0]	(4.5)	(42)	(4.5)	
Lymph Node, Mesenteric	(49)	(48)	(49)	(49)	
Hemorrhage	0.10.01	4 [4 0]	1 [4.0]		
Hyperplasia, Lymphoid Inflammation, Chronic Active	6 [3.3]	1 [4.0]			
Artery, Inflammation, Chronic Active	1 [2.0]	1 [2.0]			
Spleen	(49)	(49)	(50)	(50)	
Hematopoietic Cell Proliferation	9 [2.8]	6 [2.8]	5 [3.0]	3 [2.7]	
Lymphoid Follicle, Hyperplasia	8 [3.0]	0 [2.0]	1 [3.0]	2 [3.5]	
Thymus	(47)	(49)	(50)	(47)	
Atrophy	8 [2.9]	3 [3.0]	5 [3.2]	2 [3.5]	
Cyst	32 [1.7]	29 [1.9]	25 [1.6]	14 [1.2]	
Ectopic Parathyroid Gland	9 [1.8]	10 [1.9]	8 [1.8]	2 [1.5]	
Hyperplasia, Lymphoid		1 [3.0]	3 [2.3]		
ITEGUMENTARY SYSTEM					
Mammary Gland	(50)	(49)	(50)	(46)	
Hyperplasia, Cystic	(00)	(10)	1 [3.0]	(10)	
Skin	(50)	(49)	(50)	(50)	

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Species/Strain: MICE/B6C3F1

Route: GAVAGE

# P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

5-(HYDROXYMETHYL)-2-FURFURAL

**CAS Number:** 67-47-0

Pathologist: TOFT, J. - Blackshear, P.

Date Report Reqsted: 11/10/2006

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B6C3F1 MICE FEMALE	0 MG/KG	188 MG/KG	375 MG/KG	750 MG/KG	
MUSCULOSKELETAL SYSTEM					
Bone Fibrous Osteodystrophy Skeletal Muscle Infiltration Cellular, Lymphoid	(49) 3 [2.0] (4) 1 [3.0]	(49) 3 [3.0] (2)	(50) 1 [2.0] (1)	(50) 4 [2.3] (2)	
Infiltration Cellular, Mononuclear Cell Inflammation, Chronic Active	1 [2.0] 1 [1.0]			1 [4.0]	
NERVOUS SYSTEM					
Brain Compression Degeneration Hemorrhage	(50)	(49) 1 [3.0]	(50) 2 [3.0] 1 [2.0] 1 [2.0]	(50)	
Hydrocephalus Artery, Inflammation, Chronic Active Cerebrum, Neuron, Necrosis	1 [2.0]		1 [3.0] 1 [1.0]	1 [3.0]	
Peripheral Nerve Sciatic, Demyelination	(1)	(0)	(1) 1 [2.0]	(0)	
Spinal Cord Demyelination	(1)	(0)	(1) 1 [2.0]	(0)	
RESPIRATORY SYSTEM					
Lung Infiltration Cellular, Mononuclear Cell	(50)	(49) 1 [3.0]	(50)	(50)	
Inflammation, Chronic Active Mineralization Alveolar Epithelium, Hyperplasia	3 [1.3] 2 [1.0]	5 [2.2]		2 [2.0]	
Alveolus, Infiltration Cellular, Histiocyte Mediastinum, Infiltration Cellular, Mononuclear Cell	1 [2.0]	3 [3.0]		,	
Nose Inflammation, Chronic Active	(49)	(49) 1 [1.0]	(50) 14 [1.0]	(50) 41 [1.7]	
Glands, Dilatation Glands, Hyperplasia	12 [1.4]	7 [1.0] 36 [1.8] 7 [1.4]	48 [1.9] 48 [1.9] 42 [1.9]	41 [1.7] 47 [2.2] 43 [2.8]	

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Species/Strain: MICE/B6C3F1

Route: GAVAGE

#### P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

5-(HYDROXYMETHYL)-2-FURFURAL

**CAS Number:** 67-47-0

Pathologist: TOFT, J. - Blackshear, P.

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B6C3F1 MICE FEMALE	0 MG/KG	188 MG/KG	375 MG/KG	750 MG/KG	
Glands, Inflammation, Chronic Active Nasolacrimal Duct, Inflammation, Suppurative	1 [1.0]	6 [1.0]	21 [1.3] 2 [2.0]	38 [1.7] 3 [2.3]	
Olfactory Epithelium, Accumulation, Hyaline Droplet	1 [1.0]	1 [1.0]	27 [1.6]	25 [1.8]	
Olfactory Epithelium, Degeneration Olfactory Epithelium, Hyperplasia	2 [1.5]	1 [1.0]	34 [2.1] 8 [1.1]	24 [2.4] 24 [1.3]	
Olfactory Epithelium, Metaplasia Respiratory Epithelium, Accumulation, Hyaline Droplet	1 [1.0] 4 [1.5]	5 [1.6] 4 [1.3]	30 [1.9] 36 [2.2]	40 [4.0] 27 [1.8]	
PECIAL SENSES SYSTEM					
Eye Atrophy	(49)	(49)	(50) 2 [4.0]	(50)	
Anterior Chamber, Inflammation, Suppurative	1 [2.0]				
Cornea, Hyperplasia Cornea, Inflammation, Chronic Active	1 [3.0] 1 [2.0]		1 [2.0]	1 [2.0]	
Lens, Cataract Harderian Gland Hyperplasia Inflammation, Chronic Active	(50)	(48) 2 [3.0] 1 [2.0]	1 [4.0] (50) 4 [3.0]	(48) 2 [3.0]	
RINARY SYSTEM					
Kidney Atypia Cellular Infarct	(50)	(49) 1 [2.0] 4 [2.5]	(50) 1 [3.0]	(50)	
Infiltration Cellular, Mononuclear Cell Metaplasia, Osseous	2 (2 0)			1 [2.0]	
Mineralization Nephropathy Artery, Inflammation, Chronic Active	2 [2.0] 13 [1.0] 32 [1.1]	2 [2.0] 3 [1.0] 42 [1.1] 1 [3.0]	1 [1.0] 5 [1.0] 33 [1.0] 1 [3.0]	2 [1.0] 26 [1.2]	
Renal Tubule, Cyst Urinary Bladder	(50)	(49)	(49)	1 (50)	
Infiltration Cellular, Mononuclear Cell Artery, Inflammation, Chronic Active			1 [2.0]	1 [3.0]	

a - Number of animals examined microscopically at site and number of animals with lesion b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Test Type: CHRONIC

Species/Strain: MICE/B6C3F1

Route: GAVAGE

# P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

5-(HYDROXYMETHYL)-2-FURFURAL

**CAS Number:** 67-47-0

Pathologist: TOFT, J. - Blackshear, P.

Date Report Regsted: 11/10/2006

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Lab: BAT

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\*\*\* END OF REPORT \*\*\*

a - Number of animals examined microscopically at site and number of animals with lesion

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